

medical institution. The institution contacts the sales representative or Lilly Lecture Bureau directly. Then, Lilly's Lecture Bureau sends the specific institution their "grant request letter." See Exhibit "L." The grant request may contain a request for an honorarium to speak, as well as a request for food, beverages, travel and other expenses. LLB sends grant checks to the institution or physician within 7 days after completion of the program, and sometimes prior to the program. *Id.*

164. Further, by way of example, sales representatives could also initiate "Customer Entertainment" as a Peer to Peer Program. The sales representative invites customer physicians to specific events (i.e., sporting events, concerts, theater or dinners). If the incentive of choice was a dinner, the sales representatives were instructed to select the best items on the menu and select a red and white wine for the table." See Exhibit "M."

165. Lilly's routine practice of paying kickbacks was intended to and did amplify physicians' off-label overutilization of Zyprexa for their patients.

166. Lilly knew that the payments constituted kickbacks in reckless disregard of the law. Lilly was also acutely aware that the safe harbors established by the HHS did not cover the exorbitant payments being made. Lilly intended these payments to encourage Zyprexa overutilization in off-label demographics.

2. Illegal Off-Label Marketing to Primary Care Physicians

167. Lilly's national off-label Zyprexa marketing campaign targeting primary care physicians ("PCPs") was designed to make Zyprexa part of the everyday prescribing habits of not only LTC physicians treating the elderly, but also PCPs in their office practices.

168. In order to grow Zyprexa market share sales and surpass competing antipsychotics such as Risperdal, Lilly undertook a scheme to market and promote Zyprexa

for off-label purposes beyond LTC, Lilly concomitantly launched a marketing campaign targeting PCPs. The campaign was designed to “educate” PCPs about which patients they regularly see in their practices who present with symptoms treatable with Zyprexa, *i.e.*, albeit off-label use. Lilly’s goal being to make Zyprexa the cornerstone of PCPs everyday prescribing habits.

169. Similar to the LTC sales message, Lilly’s PCP off-label Zyprexa promotional campaign focused on symptoms, not diagnoses. To achieve this goal, Lilly PCP sales representatives were trained to deliver a Zyprexa marketing message that centered on symptoms associated with mood, thought, and behavioral disturbances.

170. Lilly targeted PCPs because of the fundamental role PCPs play in patient care and in prescribing drugs to treat a multitude of symptoms, thereby maximize profits and growing market share. In addition, Lilly marketed Zyprexa to primary care physicians for non-indicated uses, because Lilly’s marketing studies demonstrated that PCPs generally had less awareness of Lilly’s indicated uses and treatment-emergent side effects. Lilly sales material encouraged representatives to promote Zyprexa as a “safe, gentle psychotropic” suitable for people with mood-related symptoms.

171. Lilly PCP sales representatives were trained and instructed to market Zyprexa to PCPs by suggesting that there were a plethora of patients in the physician’s practice exhibiting “irritability,” “disruptive behavior,” “poor sleep,” “elevated mood,” “depressed mood,” “anxiety” and “irregular sleep patterns” and that Zyprexa is a safe and efficacious drug to treat such symptoms.

172. Just as it did for the LTC salesforce, Lilly created several promotional caricatures tailored to market Zyprexa to PCPs. The primary PCP caricature Plaintiff-Relator

became familiar with is "Donna." "Donna" is a mother of two children in her early 30's who is distracted and depressed and these symptoms are interfering with her daily life. Perhaps Donna has been prescribed drugs that treat depression. Lilly sales representatives were trained and instructed to encourage PCPs with "Donnas" in their practice to prescribe Zyprexa, although she has not been diagnosed with either bipolar mania or schizophrenia.

173. Lilly developed Donna knowing that millions of people fit Donna's broadly defined profile and who are not psychotic, schizophrenic, or bipolar. This way, Lilly could accomplish its primary goal to drive off-label sales of Zyprexa by causing as many unsuspecting adult patients on Zyprexa as possible.

174. Plaintiff-Relator has personal knowledge that Lilly's promotion of Zyprexa to PCPs, including her presence in PCP physicians' offices during a Lilly PCP sales representative's sales call.

175. Each LTC sales representative's territory "overlapped" with a Zyprexa PCP sales representative. Lilly expected its LTC representatives to coordinate with his or her overlap.

176. Accordingly, Plaintiff-Relator periodically made joint sales calls to PCPs who also treated LTC residents with her "overlap." During these joint Zyprexa sales calls, Plaintiff-Relator witnessed her Lilly PCP overlap deliver the Zyprexa off-label PCP marketing message designed to promote Zyprexa's superior efficacy and safety for treating adult patients who presented with symptoms relating to mood, anxiety, and depression, while omitting that Zyprexa is not indicated for the treatment of such symptoms not attendant to the diagnosis of bipolar disorder or schizophrenia.

177. Plaintiff-Relator witnessed the PCP overlap use, wherein the PCP sales representatives referred and relied upon the Donna profile to promote Zyprexa off-label for depression and mood disorders. At no time did the PCP sales representative initiate any discussion about Zyprexa's lack of indication for the treatment of such symptoms in patients not diagnosed with schizophrenia or bi-polar disorder.

178. Lilly's efforts to promote Zyprexa for use as a general mood stabilizer in the treatment of depression have resulted in billions of dollars of revenue for the company.

X. LILLY CAUSED THE SUBMISSION OF FALSE CLAIMS FOR ZYPREXA REIMBURSEMENT TO BE SUBMITTED BY LONG TERM CARE PHARMACIES.

A. Zyprexa Prescribed Off-label to LTC Residents Was Ineligible for Reimbursement by the Medicaid Program.

179. Prior to the enactment of the Medicare Part D program, Medicaid purchased an estimated 80-90% of atypical antipsychotic prescriptions. Of the top 30 drugs by total US revenue, Zyprexa is the most expensive. As detailed herein, the FDA defines off-label use as indications, dosage, form, dose regimen, population or other use parameter not mentioned in the approved labeling.

180. Because prescriptions for off-label uses generally are not eligible for reimbursement, under Medicaid and Medicare regulations, submission of a claim for reimbursement for a drug prescribed off-label constitutes a false claim for the purposes of the Government Plaintiffs' False Claims Acts. While it is a pharmacy, by virtue of the reimbursement system, which unwittingly submits the false prescription drug claim, the person or persons who knowingly cause(s) such a claim to be presented to the Government Plaintiffs is liable under the law. Here, Lilly's FCA violations arise from its successful attempts to induce LTC pharmacies to unwittingly defraud the government.

181. Lilly knew that medically unnecessary, off-label Zyprexa prescriptions were ineligible for Medicaid reimbursement and that its activities would, in fact, cause numerous ineligible prescriptions to be submitted to Medicaid and Medicare by the LTC pharmacies which arranged for pharmaceutical benefits to LTC patients.

182. The unwitting participation of the LTC pharmacies in the submission of false claims was not only foreseeable; it was an intended consequence of Lilly's scheme of fraud.

183. Absent Lilly's intentional, illegal off-label marketing in the LTC demographic, and its unlawful financial relationships with doctors, Zyprexa would not have been prescribed off-label. Lilly's off-label marketing programs have been extremely successful, leading to the submission of claims to the Medicare and Medicaid programs for medically unnecessary and imprudent prescriptions which otherwise would not have been paid by Medicare and Medicaid.

184. Each Zyprexa claim submitted to the Government Plaintiffs for Zyprexa prescribed for an off-label use not only violates Medicare payment rules, but constitutes the submission of a fraudulent claim redressable by the False Claims Act, 31 USC §3802, and the Plaintiff States' analogous laws.

185. The remedial provisions of the Government Plaintiffs' False Claims Act must be invoked to redress the substantial economic harm to the Medicare and Medicaid programs resulting from claims for prescriptions induced to be written and submitted by pharmacy benefits providers to the Government for reimbursement as a direct and foreseeable result of Lilly's illegal off-label marketing campaign.

186. Lilly's wanton misconduct has been ongoing since at least 2001.

XI. THE GOVERNMENT PLAINTIFFS' FALSE CLAIMS ACTS

187. The False Claims Act, 31 U.S.C. §§ 3729 to 3733, provides, in pertinent part that a person is liable to the United States Government for a civil penalty of not less than \$ 5,000 and not more than \$11,000, plus 3 times the amount of damages which the Government sustains because that person, *inter alia*,:

(a) Liability for certain acts. Any person who--

(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;

(3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;

(b) Knowing and knowingly defined. For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information--

(1) has actual knowledge of the information;

(2) acts in deliberate ignorance of the truth or falsity of the information; or

(3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

31 U.S.C. § 3729.

188. The False Claims Act defines "knowing" or "knowingly" expansively; no proof of specific intent to defraud is required. 31 U.S.C. §§3729(b)(1)-(3).

189. To cover its share of Medicaid spending, the Plaintiff States, including the State of California, enacted their own False Claims Acts. For example, California's False

Claims Act mirrors the broad proscriptions of the Federal False Claims Act. It provides in pertinent part:

§ 12651 Acts subjecting person to treble damages, costs and civil penalties; exceptions

(a) Any person who commits any of the following acts shall be liable to the state or to the political subdivision for three times the amount of damages which the state or the political subdivision sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state or to the political subdivision for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state or political subdivision for a civil penalty of up to ten thousand dollars (\$10,000) for each false claim:

- (1) Knowingly presents or causes to be presented to an officer or employee of the state or of any political subdivision thereof, a false claim for payment or approval.
- (2) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision.
- (3) Conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision.
- (7) Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision.
- (8) Is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

190. Under § 12650(b) (1) – (3) of California's False Claims Act, "Knowing" and "knowingly" mean that a person, with respect to information, does any of the following: (1) Has actual knowledge of the information, (2) Acts in deliberate ignorance of the truth or falsity of the information or (3) Acts in reckless disregard of the truth or falsity of the information. Proof of specific intent to defraud is not required.

191. In addition, as the plain language of the Government Plaintiffs' False Claims Acts make clear, a defendant need not submit a claim directly to the Government for reimbursement for liability under the Government Plaintiffs' False Claims Acts. Rather, the governing False Claim Acts apply to anyone who knowingly assists in causing the Government to pay claims grounded in fraud, without regard to whether that person directly submitted a claim to the Government.

XII. DEFENDANT LILLY'S ANTI-KICKBACK STATUTE VIOLATIONS CAUSED FALSE CLAIMS TO BE SUBMITTED TO THE GOVERNMENT.

A. The Anti-Kickback Statute.

192. The Medicare and Medicaid Fraud and Abuse Statute (Statute) was first enacted under the Social Security Act in 1977. The Statute imposes criminal penalties on whomever violates the Anti-Kickback Provision and states in relevant part,

whoever knowingly and willfully offers or pays remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person:

- (A) to refer an individual to a person for the furnishing of or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
- (B) to purchase or lease, order or arrange for or recommend purchasing, leasing, or ordering any good, facility, service or item for which payment may be made in whole or in part under a Federal Health care program.

42 U.S.C. § 1320a-7b(b)(2)(A) & (B).

193. By its terms, the Federal Medicare and Medicaid Anti-Kickback Statute prohibits certain conduct involving improper payments in connection with the delivery of goods or services, including prescription drugs, covered by Medicare, Medicaid and other federal health care programs.

194. Illegal payments or solicitations of payments include those in cash or in kind, *i.e.*, goods, those made directly or indirectly, and those made overtly or covertly.

195. A violation of the AKS arises if *one purpose* of the payment was to induce future referrals even if the payment was also intended to compensate for professional services. *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989).

196. Such illegal inducement relationships between drug companies and physicians endanger patients and harm the Government Plaintiffs because, as here, they encourage unnecessary treatments, contaminate the free exercise of medical judgment by providers, limit patient options and lead to higher federal and state payments for prescription drug benefits. The Anti-Kickback Statute was promulgated to thwart such dangerous practice of medicine.

197. The remuneration paid by Lilly and accepted by physicians all across the country, as alleged in detail *supra*, fit squarely within the AKS's definition of illegal remuneration.

198. As alleged herein, in violation of the AKS, Lilly paid, and physicians accepted, unlawful remuneration, including cash payments thinly-veiled as "speaker fees," honoraria, unrestricted educational grants and other gratuities as *quid pro quo* for volume prescription writing of Zyprexa to LTC patients, children and adults, notwithstanding Lilly's knowledge of the prohibitions of offering, paying or receiving items of value in exchange

for arranging the purchase of any good paid for in whole or in part by the federal government.

199. Lilly entered into unlawful inducement relationships in violation of the Anti-Kickback Statute with LTC physicians, PCPs, pediatric physicians and other medical professionals nationwide.

200. Although "safe harbor" regulations exist to protect certain relatively innocuous and even beneficial commercial arrangements, no such provision protects the kickbacks paid by Lilly.

201. Lilly prevented the Government Plaintiffs from knowing of AKS violations by concealing such agreements.

B. Defendant Lilly's Anti-Kickback Statute Violations are Predicate Acts Giving Rise to Liability Under the Government Plaintiffs' False Claim Acts.

202. The Anti-Kickback Statute works hand in glove with the False Claims Act. As a matter of law, violations of the AKS state a cause of action under the False Claims Act. Indeed, compliance with the AKS, as well as all other relevant laws and regulations, is a condition of payment by Medicaid for prescription drug claims. 42 U.S.C. §1320a-7b(b).

203. Thus, where conduct that violates the Anti-Kickback Act results in goods and services (here, Zyprexa) provided to Medicare and Medicaid beneficiaries, that good or service is *ineligible* for reimbursement under Medicare, Medicaid, the VA and CHAMPUS/Tricare payment rules and federal law.

204. Thus, as a matter of law, prescription drugs and other products purchased in violation of the AKS are ineligible for Government reimbursement. By and through the covert payment of illegal kickbacks, Lilly defrauded, *inter alia*, Medicaid-participating

pharmacies into presenting reimbursement claims for Zyprexa to the Government Plaintiffs containing the false certification that the claim was submitted in compliance with the AKS and other applicable regulations.

205. The Government Plaintiffs would appropriately have denied Zyprexa reimbursement claims if it had knowledge that the Zyprexa prescription giving rise to the claim was the product of an illegal kickback arrangement.

206. Defendant Lilly, acting in concert with physicians, caused, *inter alia*, Medicaid-participating pharmacies all across the country to submit claims that were rendered ineligible for reimbursement by Lilly's violations of the AKS as well as caused such pharmacies to explicitly falsely certify that they were acting in compliance with all applicable laws and regulations, including the AKS, for each and every claim the pharmacies submitted. The pharmacies' certifications Lilly caused to be submitted to the Government; however, were false when made.

207. Such pharmacies reasonably and justifiably relied upon the validity and medical appropriateness of the Zyprexa prescriptions.

208. Lilly's illegal scheme had one intended purpose and result – increasing Zyprexa profits – and therefore certified claims for Zyprexa prescriptions instead of cheaper alternatives were submitted to the Government Plaintiffs for payment by pharmacies throughout the nation. Accordingly, at all times relevant to the Complaint, Lilly acted with the requisite scienter.

209. The result of the Lilly's scheme was a dramatic increase in the number of claims submitted to the Government Plaintiffs for the higher priced Zyprexa, which led to dramatically higher revenue for Lilly. Lilly's increased revenues, and the correspondingly-

increased cost to the Government healthcare programs, were the direct, intended, and foreseeable result of the unlawful kickbacks payments made by Lilly to LTC physicians, PCPs and pediatric physicians.

210. Lilly's liability under §§ 3729(a)(1) and (a)(2) of the Federal False Claims Act, §§ 68.082(a) and the analogous laws of the Plaintiff States arises from the drug company's overt and willful participation in causing the basis for false claims to be made through the establishment of an illegal and corrupt financial relationships.

211. Lilly's conduct is also punishable under §12651 (a)(3) of the Federal False Claims Act, and the analogous provisions of the remaining Plaintiff States' laws, for entering into an unlawful conspiracies with the intent to defraud the Government.

COUNT I

False Claims Act, 31 U.S.C. §3729(a)(1) Presenting False Claims and Causing False Claims

212. Plaintiffs incorporate by reference all of the preceding paragraphs of this complaint as if fully set forth herein.

213. This Count is brought by Plaintiff-Relator Vicente in the name of the United States under the *qui tam* provisions of 31 U.S.C. §3730 et seq. for Defendant Lilly's violations of 31 U.S.C. §3729 (a)(1).

214. A significant percentage of patients who use or have been prescribed Zyprexa off-label for non-medically necessary uses as a result of Lilly's unlawful off-label marketing campaign are persons whose prescriptions are paid for in whole or in part by Medicaid, Medicare, the VA and/or CHAMPUS/Tricare.

215. At all times relevant and material to this Complaint, Lilly has induced a misallocation of Government-Plaintiffs' funds on a nationwide basis through a pattern of

fraudulent conduct, as alleged herein. Lilly intentionally concealed its national campaign to market Zyprexa for un-approved indications and medically unnecessary uses for the purpose of, and with the effect of, unlawfully increasing purchases of Zyprexa prescriptions by the Government Plaintiffs that would not have purchased by them but for Lilly's active concealment of its unlawful Zyprexa marketing campaign.

216. By the conduct alleged in this Complaint, Lilly has knowingly and foreseeably caused the submission false claims for payment or approval that Lilly knew to be ineligible for reimbursement and the cost of which would be borne by federal and state governments by and through government-funded health plans, to be presented to officers and employees of the federal and state governments. Lilly's conduct includes its deceptive and illegal scheme to expand off-label use of Zyprexa by, *inter alia*, 1) marketing Zyprexa in a misleading and/or disingenuous way for off-label uses and populations to physicians in the long term care and primary care markets and 2) orchestrating a kickback scheme pursuant to which, in sum, it paid physicians in cash and in kind in exchange for writing off-label prescriptions of Zyprexa. As a result, the United States Government paid the false claims submitted for the Zyprexa drugs by pharmacies, resulting in great financial loss to the Government Plaintiffs.

217. Lilly's conduct constitutes the intentional violation of the Federal False Claims Act.

218. By virtue of the above-described acts, among others, Lilly knowingly caused to be presented false or fraudulent claims for payment or approval, and possibly continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees, or agents of the United States, Zyprexa

219. The claims for Zyprexa caused to be submitted by Lilly constitute false claims because, *inter alia*, Medicaid/Medicare reimbursement is not available for non-medically accepted indications or non-medically necessary uses of prescription drugs as alleged herein.

220. By virtue of the above-described acts, Lilly knowingly and intentionally conspired to, and caused false claims for payment to be submitted for Zyprexa from the implementation of its kickback scheme. Lilly's kickback scheme violated the Anti-Kickback Statute and caused the submission of false claims to the Government.

221. It was the intended and foreseeable effect of Lilly's kickback scheme to cause pharmacies to routinely submit thousands false claims requesting reimbursement for expensive Zyprexa prescriptions.

222. The amounts of the false or fraudulent claims to the United States were material.

223. Plaintiff United States, being unaware of the falsity of the claims caused to be made by Defendant Lilly as alleged herein, and in reliance on the accuracy thereof, paid and may continue to pay for off-label prescriptions of Zyprexa.

224. All unlawful conduct described above may have continued after Plaintiff-Relator's voluntary decision to seek alternative employment.

225. By reason of the conduct described above, the United States' Government has been damaged in an amount that is believed to be in excess of tens of millions of dollars annually for claims submitted for Zyprexa in Northern California alone. As Defendant Lilly's fraudulent practices extended throughout the nation in states where government reimbursement rates make such fraud lucrative for the Defendant Lilly, the

amount of total damages to the government is much greater, in an amount to be proven at trial.

226. The United States *ex rel.* Plaintiff-Relator is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty of \$5,500 to \$11,000 for each ineligible claim submitted to the United States for payment.

COUNT II
False Claims Act, 31 U.S.C. §3729(a)(2)
Presenting False Statements and Records
To Get False Claims Paid

227. Plaintiffs incorporate by reference all of the preceding paragraphs of this complaint as if fully set forth herein.

228. The False Claims Act has been repeatedly violated by Defendant Lilly through the fact that its conduct knowingly resulted in claims being made under Medicaid, Medicare, the VA and CHAMPUS/Tricare which arose out of financial transactions in cash and in kind paid by Lilly in violation of the Anti-Kickback Statute. In turn, such claims were submitted to the Government by Medicaid, Medicare, the VA and or CHAMPUS/Tricare participating pharmacy benefits providers which those providers had certified as not having violated the Anti-Kickback Statute and/or other federal statutes.

229. The submission of these falsely certified claims was the intended and foreseeable result of Lilly's conduct.

230. By virtue of the above-described acts, among others, Defendant Lilly knowingly caused to be made or used false records or statements to get false or fraudulent claims paid or approved by the Government, and possibly continues to cause

false records or statements to be made or used to get false or fraudulent claims paid or approved, directly or indirectly, to officers, employees, or agents of the United States, for Zyprexa.

231. The amounts of the false or fraudulent claims to the United States were material.

232. Plaintiff United States, being unaware of the falsity of records or statements caused to be made by Lilly, and in reliance on the accuracy thereof paid and may continue to erroneously pay for Zyprexa. All unlawful conduct described above may have continued after Plaintiff-Relator Vicente's voluntary resignation from Lilly to pursue other employment.

233. By reason of the conduct described above, the United States' Government has been damaged in an amount that is believed to be in excess of tens of millions of dollars annually, at a minimum, as a direct and proximate result of paying for off-label Zyprexa reimbursement claims in Northern California alone.

234. As Defendant Lilly's fraudulent practices extend throughout the nation in states where government reimbursement rates make such fraud lucrative for Defendant Lilly, and thereby intentionally and foreseeably caused the submission of false claims for Zyprexa pursuant thereto; the amount of total damages to the government is much higher, in an amount to be proven at trial.

235. The United States *ex rel.* Plaintiff-Relator Vicente is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty of \$5,500 to \$11,000 for each ineligible claim submitted to the United States for payment.

COUNT III
False Claims Act, 31 U.S.C. §3729(a)(3)

Conspiracy to Cause False Claims, Records and Statements

236. Plaintiffs incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

237. By the foregoing acts and omissions, Defendant Lilly entered into unlawful marketing conspiracies with healthcare providers to defraud the United States by causing false and fraudulent claims to be paid and approved in violation of the False Claims Act, 31 U.S.C. §3729(a)(3).

238. By effectuating illegal financial relationships with PCP, LTC physicians and other healthcare providers throughout the nation for the purpose of increasing the number of Zyprexa prescriptions written by such healthcare providers, Defendant Lilly and health care providers not only violated the Anti-Kickback Statute but conspired to, intended to, and did defraud the United States government by causing the submission of false prescription reimbursement claims for Zyprexa.

239. Defendant Lilly committed overt acts in furtherance of its conspiracies as alleged *supra*, including Defendant Lilly's payments of kickbacks.

240. The false or fraudulent claims caused to be submitted to the Government as a direct and proximate result of Lilly's conspiracies were material.

241. Plaintiff United States, being unaware of the falsity of the claims and/or statements caused to be submitted by Lilly and its co-conspirators, and in reliance on the accuracy thereof, paid and may continue to pay for Zyprexa. All unlawful conduct described above may have continued after Plaintiff-Relator voluntarily resigned from her employment with Lilly to pursue alternative employment.

242. As the Defendant Lilly's fraudulent practices extend throughout the

nations in states where government reimbursement rates make such fraud lucrative for Defendant Lilly, and caused the submission of false claims for Zyprexa pursuant thereto, the amount of total damages to the government amounts to hundreds of millions of dollars, to be proven at trial.

243. The United States *ex rel.* Plaintiff-Relator is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty of \$5,500 to \$11,000 for each ineligible claim presented to the United States for payment.

COUNT IV
Florida False Claims Act
Fl. Stat. §§68.081-68.09

244. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Vicente in the name of the State of Florida under the *qui tam* provisions of Florida False Claims Act, Fl. Stat. §§68.081-68.09.

245. Defendant Lilly at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Florida, including Zyprexa.

246. By virtue of the above-described acts, among others, Defendant Lilly intentionally and willfully caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Florida, for Zyprexa.

247. The amounts of the false or fraudulent claims to the State of Florida were material.

248. Plaintiff State of Florida, being unaware of the falsity of the claims caused to be submitted by the Defendant Lilly, and in reliance on the accuracy thereof paid and continues to pay for ineligible Zyprexa prescription reimbursement claims. By reason of Defendant Lilly's wrongful conduct, this State has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under its False Claims Act, to be determined at trial, plus the maximum penalties for each such false statement and/or records caused to be made or used by Defendant Lilly and each such false claim caused to be submitted by Defendant Lilly.

COUNT V
Conspiracy to Submit False Claims in Violation of
The Florida False Claims Act
Fl. Stat. §68.082(2)(C)

249. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

250. Defendant Lilly at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Florida, including Zyprexa.

251. As is alleged herein, physicians entered into unlawful conspiracies with Defendant Lilly pursuant to which, *inter alia*, Lilly paid kickbacks to physicians in exchange for writing off-label prescriptions of Zyprexa. Lilly and physicians entered into conspiracies willfully and intentionally.

252. By entering the illegal kickback agreement detailed herein, Lilly and physicians conspired to defraud the State of Florida by causing the submission of false claims for Zyprexa.

253. As a result of the claims for reimbursement Lilly and physicians caused to be submitted to Florida Medicaid pursuant to their conspiracies, all of which contained

falsely certifications of compliance with federal and state Medicaid law and regulation as a condition of reimbursement paid to pharmacy benefit providers for Zyprexa, Florida through its Medicaid program regularly made payments to pharmacies for Zyprexa.

254. The amounts of the false or fraudulent claims to the State of Florida were material.

255. Plaintiff State of Florida, being unaware of the falsity of the claims and/or statements caused to be made by Lilly and its co-conspirators, and in reliance on the accuracy thereof paid and may continue to pay for Zyprexa. All unlawful conduct described above may have continued after Plaintiff-Relator voluntary left Lilly's employ.

COUNT VI
Illinois Whistleblower Reward and Protection Act
740 ILCS 175/1 et seq.

256. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Vicente in the name of the State of Illinois under the *qui tam* provisions of 740 ILCS 175/4 for Defendant Lilly's violation of 740 ILCS 175/3.

257. Defendant Lilly at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Illinois, including Zyprexa.

258. By virtue of the above-described acts, among others, Defendant Lilly knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Illinois, for Zyprexa.

259. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

260. The amounts of the false or fraudulent claims to the State of Illinois were material.

261. Plaintiff State of Illinois, being unaware of the falsity of the claims caused to be submitted by the Defendant Lilly, and in reliance on the accuracy thereof paid, and continues to pay, ineligible claims for reimbursement for off-label uses of Zyprexa. By reason of Defendant Lilly's wrongful conduct, this State has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under its False Claims Act, to be determined at trial, plus the maximum penalties for each such false statement and/or records caused to be made or used by Defendant Lilly and each such false claim caused to be submitted by Defendant Lilly.

COUNT VII

California False Claims Act Ca. Government Code §12650 *et seq.*

262. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Vicente in the name of the State of California under the *qui tam* provisions of the California False Claims Act, California Government Code §12651(a).

263. Defendant Lilly at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals, including Zyprexa, in the State of California.

264. By virtue of the above-described acts, among others, Defendant Lilly knowingly caused to be presented false or fraudulent claims for payment or approval, and